PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	14 NOV 2005
Applicant's or agent's file reference 0311241	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US04/26759	19 August 2004 (19.08.2004)	19 August 2003 (19.08.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 6/00 and US Cl.: 600/476, 477

Applicant

CEDARS-SINAI MEDICAL CENTER

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	13 October 2005 (13.10.2005)	For Julianne M. Sullivan Telephone No. 571-272-6084

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 6, 15, 21-24, 32, 33, 42, 43	YES
	Claims 1-5, 7-14, 16-20, 25-31, 34-41, 44	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-44	NO
Industrial applicability (IA)	Claims 1-44	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1-5, 7-14, 16-20, 25-31, 34-41 and 44 lack novelty under PCT Article 33(2) as being anticipated by Marcu et al. (U.S. Patent No. 6,272,376).

Marcu et al. teaches a method and system, including a computer-readable medium and an instrument for carrying out the method, for characterizing a sample by estimating a fluorescence impulse response based upon Laguerre expansion coefficients, where the sample is a biological tissue, a chemical, a biochemical sample, or a combination thereof, predicting a concentration of at least one biochemical component of the sample, analyzing compositional and functional changes in the sample, distinguishing normal from tumor tissue, characterizing the composition of an atherosclerotic plaque, and monitoring an intracellular component and its activity, where markers are used to predict plaque vulnerability and rupture, computing a map of fluorescence lifetimes by constructing an impulse response function (col. 1, lines 9-29, col. 2, lines 15-44, col. 4, lines 28-67, col. 5, lines 1-8, col. 7, lines 12-56, col. 8, lines 21-54, col. 11, lines 33-67 and col. 12, lines 1-19 and 54-67).

Claims 6 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Marcu et al. in view of Benaron et al. (U.S. Patent No. 5,762,609).

Marcu et al. teaches all of the features of the present invention except for expressly disclosing that the instrument used is one of a spectrophotometer, a cytometer or a drug discovery analysis system. In the same field of endeavor, Benaron et al. teaches characterizing a sample with fluorescence data by using a spectrophotometer (col. 4, lines 13-25, col. 5, lines 20-27 and col. 9, lines 13-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used a spectrophotometer as in Benaron et al. with the system of Marcu et al. in order to improve efficiency because it is an instrument that is capable of multiple types of measurements and functions.

Claims 21-23, 32 and 42 lack an inventive step under PCT Article 33(3) as being obvious over Marcu et al. in view of Lemelson (U.S. Patent No. 5,464,013).

Marcu et al. teaches all of the features of the present invention except for expressly disclosing identifying a chemical with a biological activity for automated screening of the sample for new drug discovery, characterizing the drugs based on their chemical composition and characterizing a biochemical assay based on the biochemical contents. In the same field of endeavor, Lemelson teaches developing drugs by identifying chemicals with biological activity for automated screening of a sample, characterizing the drugs based on their chemical composition and characterizing a biochemical assay based on the biochemical contents (col. 23, lines 15-50, col. 26, lines 61-67 and col. 27, lines 1-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Lemelson for drug discovery with those of Marcu et al. in order to provide improved analysis of the efficacy of newly developed drugs.

Claims 24, 33 and 43 lack an inventive step under PCT Article 33(3) as being obvious over Marcu et al. in view of Fisher et al. (U.S.

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Supplemental Box
In case **the space in any of the preceding boxes is not sufficient.**

Patent No. 5,998,597).

Marcu et al. teaches all of the features of the present invention except for expressly disclosing sequencing a deoxyribonucleic acid microarray. In a related field of endeavor, Fisher et al. teaches a method of improving selectivity in photo-activation in molecular agents that includes sequencing of DNA (col. 25, lines 22-63). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the techniques of Fisher et al. in the system of Marcu et al. in order to improve the resolution of the characterization of the samples.

Claims 1-44 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.